REMARKS

Claims 23 and 32-43 are pending. The Examiner rejected claims 23 and 32-43 under 35 U.S.C. § 102(b). Claims 23 and 32-43 have been amended herein. New claims 44-46 have been added. Support for the amendments and new claims may be found throughout the specification, e.g., at pages 3, 6, and 9-10. No new matter has been added. Thus, claims 23 and 32-46 are pending.

In light of the amendments and the remarks herein, Applicants respectfully request examination and allowance of claims 23 and 32-46.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 23 and 32-43 under 35 U.S.C. § 102(b) over Sanders *et al.*, U.S. Pat. 5,766,605, stating in particular that "Applicant argues that Sanders et al. does not disclose a composition containing combinations of botulinum toxin, a local anesthetic, and a local vasoconstrictor. . . . [R]egardless of the 10-minute time lag, the composition is anticipated since the three ingredients are administered sequentially. . . . There do not appear to be any unexpected results when the composition of botulinum toxin, a local anesthetic, and a vasoconstrictive agent is admixed in a container."

Applicants respectfully disagree with the rejection as applied to the pending claims. Claims 23, 37, and 42, as presently amended, recite an article of manufacture comprising an admixture of a botulinum toxin and either a local anesthetic agent or a local vasoconstrictive agent, or both. New claim 44 recites that the articles of claim 23, 37, and 42 further comprise packaging material. New claim 45 recites that the packaging material comprises a label that indicates that the admixture is useful for treating a patient having an acute skin wound. New claim 46 recites that the label further indicates that local administration of the admixture enhances healing of the skin wound.

At no point does Sanders *et al.* disclose or suggest an article of manufacture comprising an admixture containing botulinum toxin and a local anesthetic agent and/or a local vasoconstrictive agent, as recited in the presently amended claims. Rather, the Sanders *et al.*

patent discloses a method for the control of autonomic nerve function that involves administering a therapeutically effective amount of botulinum toxin such that denervation of the neurons is achieved. In the cited passage of the Sanders *et al.* patent (column 8, lines 21-31), a sedative, a decongestant, a local anesthetic, and botulinum toxin were sequentially administered. Sequential administration of a botulinum toxin, a local anesthetic, and a local vasoconstrictive agent does not teach or suggest an article of manufacture comprising an admixture of a botulinum toxin, a local anesthetic, and a local vasoconstrictive agent. Applicants strongly disagree with the Examiner's assertion that sequential administration of the three components either: 1) results in the formation of a composition comprising the three components in the nasal passages of a dog; or 2) teaches that such a composition would be useful. Indeed, even if sequential administration did result in the formation of such a composition in the dog's nasal passages, the fact that Sanders *et al.* disclose separate administrations of each composition over a 10 minute time lag teaches away from an article of manufacture comprising an admixture of the three components for simultaneous administration.

Furthermore, Sanders *et al.* does not teach or in any way suggest such an article of manufacture that further comprises packaging material, particularly packaging material that includes a label that indicates that the admixture is useful for treating a patient having an acute skin wound or that indicates that local administration of the admixture enhances healing of the skin wound. In the cited passage of the Sanders *et al.* patent (Example IV, column 8, lines 21-37), experiments were done to confirm that botulinum toxin is an effective long-term therapy for vasomotor rhinitis, which is characterized by "a copious flow of clear, watery secretions" that result from excessive parasympathetic activity. See column 1, lines 37-41 and column 7, lines 22-26 of the Sanders *et al.* patent. Applicants submit that the sequential administration of a botulinum toxin, a local anesthetic, and a local vasoconstrictive agent to treat vasomotor rhinitis does not teach or suggest an article of manufacture comprising an admixture of the three components having packaging material and/or a label directed to treatment of skin wounds, as presently recited.

In light of the above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

CONCLUSION

Given all of the above, Applicants respectfully assert that the pending claims are in condition for allowance, which action is requested. The Examiner is invited to telephone the under-signed attorney if such would expedite prosecution.

Enclosed is a $548.00 check for payment of the Request for Continued Examination ($385.00), multiple dependent claim fee ($145.00) and excess claim fee ($18.00). Also enclosed is a $210.00 check for a Two-Month Extension of Time fee. Please apply any deficiencies or credits to Deposit Account No. 06-1050

Respectfully submitted,

Date: 10/16/03

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